

# PATENT COOPERATION TREATY

From the Japan Patent Office

(INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY)

## PCT

To: Agent of Applicant

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### WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing (day/month/year) <span style="float: right;">28.6.2005</span>	
Applicant's or agent's file reference <span style="float: right;">09651</span>	<b>REPLY DUE</b> within 2 months from the above date of mailing
International application No. PCT/JP2004/008471	International filing date (day/month/year) 10.06.2004
Priority date (day/month/year) 10.06.2003	
International Patent Classification (IPC) <span style="float: right;">Int. Cl<sup>7</sup></span> <span style="float: right;">G01N33/53</span>	
Applicant <div style="text-align: center;">DAINIPPON PHARMACEUTICAL CO., LTD.</div>	
<p>1. <input checked="" type="checkbox"/> The written opinion drawn up by the International Searching Authority is regarded a written opinion of the International Preliminary Examining Authority. <input checked="" type="checkbox"/> yes <input type="checkbox"/> no</p> <p>2. This <u>second</u> report contains indications relating to the following items:</p> <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Box No. I      Basis of the opinion  <input type="checkbox"/> Box No. II      Priority  <input checked="" type="checkbox"/> Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  <input type="checkbox"/> Box No. IV      Lack of unity of invention  <input checked="" type="checkbox"/> Box No. V      Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement  <input type="checkbox"/> Box No. VI      Certain documents cited  <input type="checkbox"/> Box No. VII      Certain defects in the international application  <input type="checkbox"/> Box No. VIII      Certain observations on the international application                 </div> <p>3. The applicant is hereby invited to reply to this opinion.</p> <p><b>When?</b> See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d). An extension is granted only when a rational reason exists and schedule is not full.</p> <p><b>How?</b> By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.</p> <p><b>Also</b> For an additional opportunity to submit amendments, see Rule 66.4.                      For the examiner's obligation to consider amendments and/or argument, see Rule 66.4bis.                      For an informal communication with the examiner, see Rule 66.6.</p> <p><b>If no reply is filed</b>, the international preliminary examination report will be established on the basis of this opinion.</p> <p>4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: <u>21.10.2005</u></p>	

Name and mailing address Japan Patent Office (IPEA/JP) 4-3, Kasumigaseki 3-chome Chiyoda-ku, Tokyo 100-8915 Japan	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%; padding: 5px;">                             Authorized officer                              Examiner  <div style="text-align: right;">Shoko Yamamura</div> </td> <td style="width: 30%; padding: 5px;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">2J</td> <td style="width: 50%; text-align: center;">9217</td> </tr> </table> </td> </tr> <tr> <td colspan="2" style="padding: 5px;">                             Telephone No. 03-3581-1101 extension 3252                         </td> </tr> </table>	Authorized officer Examiner <div style="text-align: right;">Shoko Yamamura</div>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">2J</td> <td style="width: 50%; text-align: center;">9217</td> </tr> </table>	2J	9217	Telephone No. 03-3581-1101 extension 3252	
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**WRITTEN OPINION OF THE INTERNATIONAL  
PRELIMINARY EXAMINING AUTHORITY**

Intern. application No. PCT/JP2004/008471

**I. Basis of the opinion**

1. Unless otherwise indicated under this item, this written opinion was drawn up based on the language in which the international application was filed.

☐ This written opinion is in the following language \_\_\_\_\_ which is:

☐ the language of a translation furnished for the purposes of the international search (under Rule 12.3 and 23.1(b)).

☐ the language of publication of the international application (under Rule 12.4).

☐ the language of a translation furnished for the purposes of the international preliminary examination (under Rule 55.2 and/or 55.3).

2. This opinion has been drawn up on the basis of (Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".):

☐ the international application as originally filed.

☒ the description: pages 1-29, as originally filed  
pages \_\_\_\_\_, received by the International Preliminary  
Examining Authority on \_\_\_\_\_  
pages \_\_\_\_\_, received by the International Preliminary  
Examining Authority on \_\_\_\_\_

☒ the claims: Nos. 2-11, 15-23, 25, as originally filed  
Nos. \_\_\_\_\_, as amended under Article 19 PCT  
Nos. 1, 12, 13, 14, 24, received by the International Preliminary  
Examining Authority on 08.04.2005  
Nos. \_\_\_\_\_, received by the International Preliminary  
Examining Authority on \_\_\_\_\_

☒ the drawings: pages/Figs. 1-4, as originally filed  
pages/Figs. \_\_\_\_\_, received by the International Preliminary Examining  
Authority on \_\_\_\_\_  
pages/Figs. \_\_\_\_\_, received by the International Preliminary Examining  
Authority on \_\_\_\_\_

☐ the sequence listing or related table  
see supplementary column relating to sequence listing,

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, page \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/fig \_\_\_\_\_

☐ the sequence listing (specify) \_\_\_\_\_

☐ the table relating to sequence listing (specify) \_\_\_\_\_

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

☐ the description, page \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/fig \_\_\_\_\_

☐ the sequence listing (specify) \_\_\_\_\_

☐ the table relating to sequence listing (specify) \_\_\_\_\_

**WRITTEN OPINION OF THE INTERNATIONAL  
PRELIMINARY EXAMINING AUTHORITY**

Intern. application No.PCT/JP2004/008471

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 22 and 23

because:

- ☒ the said international application, or the said claim No(s). 22 and 23 relate to the following subject matter which does not require an international preliminary examination (specify):

The invention described in claims 22 and 23 is that of a commercial method and an advertising method and consequently falls under methods of business activities. Claims 22 and 23 relates to a subject matter which does not require an international preliminary examination by the International Preliminary Examining Authority under PCT rule 67.1 (iii).

- ☐ the description, claims or drawings (indicate particular elements below) or said claims Nos. is (are) so unclear that no meaningful opinion could be formed (specify):
- ☐ the claims or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 22 and 23
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C (guideline for preparing specification etc containing base sequence and/or amino acid sequence) of the Administrative Instructions In that:
- |                            |  |
|----------------------------|--|
| the written form           | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ have not been furnished
- ☐ do not comply with the technical requirements
- ☐ See separate sheet for further details.

**WRITTEN OPINION OF THE INTERNATIONAL  
PRELIMINARY EXAMINING AUTHORITY**

International application No.  
PCT/JP2004/008471

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-11, 24, 25</u>	YES
	Claims <u>12-21</u>	NO
Inventive Step (IS)	Claims <u>1-11</u>	YES
	Claims <u>12-21, 24, 25</u>	NO
Industrial Applicability (IA)	Claims <u>1-21, 24-25</u>	YES
	Claims _____	NO

2. Citations and Explanations

Reference 1: CHEST Vol.123, No.5 (May 2003) p.1375-1378

Claims 12-21, 24 and 25

Reference 1 describes use of a monoclonal antibody specific to D-dimer, for the measurement of D-dimer level in patients suspected to have acute aortic dissection.

The reagent described in claims 12-21 is considered to contain an antibody that recognizes D-dimer suitable for the evaluation of the diseases described in each of these claims. On the other hand, a monoclonal antibody specific to the D-dimer described in Reference 1 is the same as the antibody of claims 12-21 as a substance, and is not considered to be a form unsuitable for the evaluation of the diseases described in claims 12-21.

Therefore, the invention relating to claims 12-21 lacks novelty (see PCT international search and international preliminary examination Guideline 5.23).

In addition, use of an antibody for the production of a reagent is expected to be done by those of ordinary skill in the art.

Claims 1-11

Determination of possibility of having developed acute aortic dissection when the measured D-dimer concentration is not less than the blood D-dimer cut-off value pre-established between acute aortic dissection and acute myocardial infarction, and determination of the onset of Stanford type A acute aortic dissection, Stanford type B acute aortic dissection or acute myocardial infarction based on the measurement of the D-dimer concentration are not described in any of the references cited in the International Search Report, nor are they obvious to those of ordinary skill in the art.